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FOX ROTHSCHILD LLP 1101 MARKET STREET PHILADELPHIA, PA 19107			CUTLIFF, YATE KAI RENE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,682

Applicant(s)

ISSBERNER ET AL.

Examiner

YATE' K. CUTLIFF

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 3 - 20 are pending.
Claims 1 and 2 have been canceled
Claims 3—20 are rejected.

Response to Amendment

2. The amendment to claims 3, 4, 5 and 6, submitted October 17, 2008 is acknowledged and entered.

Response to Arguments

3. Applicant's arguments, see page 6, filed October 17, 2008, with respect to claim 6 have been fully considered and are persuasive in view of the amendment. The objection of claim 6 has been withdrawn.
4. Applicant's arguments, see pages 7 and 8, filed October 17, 2008, with respect to claims 1, 2, 4 and 5 have been fully considered and are persuasive; and in view of the cancellation of claims 1 and 2, and the amendment of claims 4 and 5. The 35 U.S.C. 102(b) rejections of claims 1, 2, 4 and 5 have been withdrawn.
5. Applicant's arguments with respect to the 35 U.S.C. 103(a) rejections of claims 1, 3, 6-10 and 11-20 have been considered but are moot in view of the new ground(s) of rejection as set out below.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindner (US 4,332,702) in view of Hurwitz, et al. (US 2,975,152).

10. The rejected claim covers a fatty acid ester mixture of pentaerythritol, a pentaerythritol oligomer, or mixtures thereof, wherein the fatty acid component is a mixture containing from about 40% to about 50% by weight of a C16 fatty acid and from about 45% to about 55% by weight of a C18 fatty acid, and wherein the ester contains less than 0.3% by weight C17 fatty acid acyl groups and has a melting point of at least 30°C.

11. Lindner discloses a partial ester of pentaerythritol, in column 2, lines 13-20 wherein the fatty acid components overlap with Applicant's claimed fatty acid range.

The difference between Applicant's ester and that of Lindner is the claimed melting point.

However, Hurwitz et al. discloses esters of pentaerythritol that have melting points of not over 35°C. (see column 1, lines 15-23) The Hurwitz et al. esters are made from monocarboxylic acids containing not more than 18 carbon atoms. (see column 3, lines 1-3 & list of columns 5-6).

In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In this instance the fatty acid component of the prior art encompasses the fatty acid content of Applicant's claimed mixture.

Therefore, the claim is obvious.

12. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindner (US 4,332,702) in view of Hurwitz, et al. (US 2,975,152).

13. The rejected claim covers a fatty acid ester mixture of pentaerythritol, a pentaerythritol oligomer, or mixtures thereof, wherein the fatty acid component has 6 to 22 carbon atoms, and wherein the ester contains less than 0.3% by weight C17 fatty acid acyl groups and has a melting point of at least 30°C with a percentage content of (a) from about 10% to about 25% by weight monoesters, (b) from about 25% to about 40% by weight diesters, and (c) from about 30% to about 45% by weight triesters.

14. Lindner discloses an ester of pentaerythritol, in column 2, lines 21-25 wherein the mixture has a percentage content of monoester, diester and triester overlap with Applicant's claimed ester content.

The difference between Applicant's ester and that of Lindner is the claimed melting point.

However, Hurwitz et al. discloses esters of pentaerythritol that have melting points of not over 35°C. (see column 1, lines 15-23) The Hurwitz et al. esters are made from monocarboxylic acids containing not more than 18 carbon atoms. (see column 3, lines 1-3 & list of columns 5-6).

In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In this instance the percentage content of the esters of the prior art encompasses the fatty acid content of Applicant's claimed mixture.

Therefore, the claim is obvious.

15. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai et al. (US 4113,635) in view of in view of Hurwitz, et al. (US 2,975,152).

16. The rejected claim covers a fatty acid ester mixture of pentaerythritol, a pentaerythritol oligomer, or mixtures thereof, wherein the fatty acid component has 6 to 22 carbon atoms, and wherein the ester contains less than 0.3% by weight C2 fatty acid acyl groups and has a melting point of at least 30°C with a percentage content of (a) from about 12% to about 19% by weight monoesters, (b) from about 25% to about 35% by weight diesters, (c) from about 30% to about 40% by weight triesters, and (d) from about 6 to about 11% by weight tetraesters.

17. Sakurai et al. states that the fatty acids used to produce the corresponding partial esters by the reaction with pentaerythritol are from animal oil, vegetable oils, and straight chain fatty acids i.e. capric, undecanoic, lauric, myristic, palmitic, stearic and olefinic fatty acids. (see column 3, lines 40-51). Example 3 discloses pentaerythritol esters that are 20% monoester, 30% diester, 40% triester and 10% tetraester. The ranges in Examples 3 overlap Applicant's claimed ranges for the diester, triester and tetraester, and is close to the monoester range.

The difference between Applicant's ester and that of Lindner is the claimed melting point.

However, Hurwitz et al. discloses esters of pentaerythritol that have melting points of not over 35°C. (see column 1, lines 15-23) The Hurwitz et al. esters are made from monocarboxylic acids containing not more than 18 carbon atoms. (see column 3, lines 1-3 & list of columns 5-6).

A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have

expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.). (MPEP 2144.05(I)). In this instance the percentage content of the mono- di- and tri- esters of the prior art encompasses the fatty acid content of Applicant's claimed mixture, with the percentage content of the monoester of the prior art being different by 1 percentage.

Therefore, the claim is obvious.

18. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konen et al. (Oil & Soap, 1945, vol. 22), in view of Barth et al. (US 2,441,555), in view of in view of Cooper et al. (US 5,304,665) and further in view of Barsky (Us 2,705,722).

19. The rejected claims cover, inter alia, a process for production of a C16/C18 fatty acid ester of pentaerythritol, comprising (A) providing about 1.8 to about 2.2 mol of a fatty acid mixture per mol of pentaerythritol wherein the fatty acid mixture comprises from about 40% to about 50% by weight of a C16 fatty acid and from about 45% to about 55% by weight of a C18 fatty acid; (B) esterifying component (A) at temperatures ranging from about 180°C to about 250°C in an inert gas atmosphere in the absence of solvent to form a reaction mixture; and (C) stirring the reaction mixture *in vacuo* until it has an acid value of less than 1 and an OH value of 145 to 158. The dependent claims

disclose standard esterification process steps, the addition of hydrogen peroxide to the reaction mixture, and the fatty acid mixture material.

20. Konen et al. states that the best method for ester formation by reaction of polyhydric alcohol and fatty acids is with heat under vacuum, fatty acid and the theoretical amount, plus 5%, of alcohol at 450°F (232.22°C), SO₂, inert gas, or steam is bubbled through rapidly to provide agitation and carry off water. (see page 58, column 1, paragraph 4). An example of the polyhydric alcohol used in the process is pentaerythritol and produces a product with an acid value of 1 to 2. Additionally, the oil used was a linseed or soybean fatty acid. (see page 59 column 1, paragraph 2 & Table 1).

Konen et al. does not disclose the following: the molar ratio of acid to alcohol mixture; the OH value in the reaction mixture; the fatty acid mixture composition of the; removing water from the reaction mixture by distillation; treating the reaction mixture with hydrogen peroxide; and removing the unreacted pentaerythritol by filtration.

With regard to the OH value in the reaction mixture, Konen et al. does not give the value but states that free hydroxyl would be left in a reaction between fatty acid molecules and polyhydric alcohols if excess of the alcohol were used. (see page 57, column 2, paragraph 1).

With regard to the esterification process involving an ester mixture, Barth et al. discloses a process for the preparation of mixed esters which involves partial esters of pentaerythritol. The process of Barth et al. uses one molecular portion of pentaerythritol with from one to three molecular proportions of a higher fatty acid. (see column 2,

Example 1). The fatty acids suitable for the process of Barth et al. are long-chain fatty acids having 10 or more carbon atoms per molecule. (see column 2, lines 17-30).

With regard to the removal of water by distillation, it is stated in Cooper et al. that with the normal process of direct esterification the water generated by the reaction of fatty acid and alkoxyated polyol is continuously removed by distillation. (see column 2, lines 14-21). Further, Konen, states that if an insoluble alcohol is used in the esterification process the water may be distilled off. (see page 57, column 2, lines 4-5 from top).

With regard to treating the reaction mixture with hydrogen peroxide, Barsky discloses a refining process where hydrogen peroxide is add to the crude esters made from polyhydric alcohols to bleach the ester if the color is dark. (see column 1, lines 36-40, lines 49-59 and claim 1).

With regard to the removal of the unreacted pentaerythritol by filtration, this would appear to be drawn to the work up of the final product since Cooper et al. and Konen discloses that water can be removed by distillation. This claim step appears to be well within the purview of one having ordinary skill in the art. Thus dependent claim 8 is drawn to routine process steps which a skilled artisan would be motivated to do in order to make the process more efficient.

The main process steps of Applicant's claimed invention, esterification of C16 and C18 mixture of fatty acids with pentaerythritol is disclosed in Konen et al. and the teachings of Barth et al. suggest that the process of Konen can be used to produce a mixture of fatty acid pentaerythritol esters. Additionally, the other refining process steps

used by Applicant are routine to an esterification process and are disclosed by the prior art references of Cooper et al. and Barsky. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a C16/C18 fatty acid pentaerythritol ester as suggested by Konen in view of Barth and incorporate the remaining processing steps as set out in Cooper et al. and Barsky to obtain the desired pentaerythritol ester.

Therefore, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements of Konen, Barth, Cooper and Barsky as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. *KSR International Co. v. Teleflex Inc.*, 550 U.S., 82 USPQ2d 1385 (U.S. 2007).

With regard to the composition of the fatty acid mixture being a certain percentage of C₁₆ and C₁₈ fatty acid because of the teaching of Barth, where it is disclosed that mixed esters of pentaerythritol can be made; one having ordinary skill in the art at the time the invention was made would have found it obvious to modify the parameters in order to determine the optimum reaction conditions, to effect the ratio of the fatty acid in the ester. Therefore, the ratio of C₁₆ and C₁₈ fatty acid in the pentaerythritol ester can be affected via routine experimentation by the ordinary artisan skilled in the art. When the general condition of a claim are disclosed in the prior art, it is not inventive to discover optimum of workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

21. Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirose et al. (US 5,436,006), in view of Bradley (US 1,951,593), in view of Hurwitz, et al. (US 2,975,152), in view of Sakurai et al. (US 4,113,635), in view of Miranol Chemical Co., Inc. (EP 0163806 A1) (Miranol) and further in view of Kahre et al. (US 6,432,419).

22. The rejected claims cover, inter alia, a cosmetic and/or pharmaceutical composition comprising an ester formed by esterification of pentaerythritol, a pentaerythritol oligomer, or mixtures thereof with C6-22 fatty acids, wherein the ester contains less than 0.3% by weight C17 fatty acid acyl groups and has a melting point of at least 30°C. Dependent claims 12-19 disclose additional components of the cosmetic or pharmaceutical composition. Dependent claim 20 further limits the composition.

23. Hirose et al. discloses lanolin-like synthetic oil composition which can be produced by the esterification of long-chain linear fatty acid with a polyhydric alcohol. (see column 2, lines 9-16). The long chain fatty acids are those having 15 to 28 carbon atoms, preferably 18 to 28. The esterification reaction can be carried out with or without a catalyst. The product of Hirose et al. can be combined with oily substances such as olive oil which is liquid at room temperature (approx. 28°C). (see column 4, line 50-51). The product of Hirose et al. can be mixed with bees wax, Vaseline, liquid paraffin, waxes, surfactants, higher fatty acids, higher alcohols, polyhydric alcohols etc. (see column 4, lines 50-67 and Table 4). Further, Table 1, materials L-4 to L-8. The products were prepared by the process in Example 1 where a mixture of fatty acids was reacted with glycerol. Further, Table 4 discloses products made with the ester of Hirose et al.

where the ester is 4.0 molar percent of the cosmetic composition, which includes oil, fatty alcohol, partial glyceride, oligoglucoside and water.

The difference between Applicant's claimed process and the prior art reference of Hirose et al. is that the reference does not disclose the following product features: melting point; the ratio of mono-, di- and tri- ester in the ester mixture; and specifically identifies the oligoglycosides.

However, Hurwitz et al. discloses esters of pentaerythritol that have melting points of not over 35°C. (see column 1, lines 15-23) The Hurwitz et al. esters are made from monocarboxylic acids containing not more than 18 carbon atoms. (see column 3, lines 1-3 & list of columns 5-6).

With regard to the ratio of mono-, di- and tri- ester in the ester mixture, Sakurai et al. discloses that esterification of fatty acids with pentaerythritol preferably produce mono-, di- and tri substituted esters and the partial esters are useful in industry. Further, Hirose et al. states that polyhydric alcohols can be used when esterifying the product containing fatty acids having medium chain length, long-chain fatty acid and dibasic acid having medium chain length. (see column 2, lines 9-15). Bradley teaches that in preparing mixed esters pentaerythritol can replace glycerol. (see column 1, lines 96-99). Furthermore, Miranol discloses a mixture of oligomers of pentaerythritol which have been esterified which are useful in cosmetics such as those disclosed in Examples 8-12, where the content of the mixed ester in the cosmetic ranges from 4.0 to 5.0.

With regard to the oligoglycosides being alkyl and alkenyl, Kahre et al. discloses a cosmetic and/or pharmaceutical preparation that uses fats, and uses nonionic

surfactants of alkyl and/or alkenyl oligoglycoside to improve the sensorial properties of the fatty compounds. (see column 3, lines 35-39).

Applicant's claim is to a cosmetic and/or pharmaceutical composition comprising esters of pentaerythritol produced by an esterification process. The references of Hirose et al., Bradley, Hurwitz, et al., Sakurai et al. and Miranol in view of Kahre et al. suggest esters of pentaerythritol and/or the mixtures thereof, and the esters having use in industry and one of those industries being the cosmetics industry.

Applicant is reminded that claim 11 is claimed in a Product-by-Process format. The PTO takes the following position with respect to Product- by-Process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698,227 USPQ 964, 966 (Fed. Cir. 1985). The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221,223 (CCPA 1979). "The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when

a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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